Celgene Corporation, Lichen Teng Employee of: Celgene Corporation, Arthur Kavanaugh Grant/research support from: UCB Pharma
DOI: 10.1136/annrheumdis-2019-eular.1860

AB0738

DUAL NEUTRALISATION OF INTERLEUKIN (IL)-17A AND IL-17F WITH BIMEKIZUMAB IN MODERATE-TO-SEVERE PLAQUE PSORIASIS: 60-WEEK RESULTS FROM A RANDOMISED, DOUBLE-BLINDED, PHASE 2B EXTENSION STUDY

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Background: Psoriasis is a chronic, systemic, immune-mediated inflammatory disease associated with prominent skin manifestations. One in four patients with psoriasis also has psoriatic arthritis,¹ with skin disease preceding joint manifestations in most patients.² Interleukin (IL)-17F shares structural homology and pro-inflammatory function with IL-17A. Preclinical and early clinical data support dual neutralisation of IL-17F, together with IL-17A, as a novel targeting approach for the treatment of immune-mediated inflammatory diseases. Bimekizumab, a monoclonal antibody that potently and selectively neutralises both IL-17A and IL-17F, is in development for the treatment of psoriasis, psoriatic arthritis and ankylosing spondylitis.³⁻⁵ In the 12-week BE ABLE 1 study (NCT02905006), bimekizumab provided rapid and substantial clinical improvements in patients with moderate-to-severe plaque psoriasis, with a safety profile consistent with previous bimekizumab studies.³

Objectives: The objectives of this Phase 2b extension study (BE ABLE 2; NCT03010527) were to assess the long-term safety and efficacy of subcutaneous bimekizumab every four weeks for an additional 48 weeks (60 weeks' total exposure).

Methods: BE ABLE 1 responders ($\geq 90\%$ reduction in Psoriasis Area Severity Index [PASI90] at Week 12) receiving placebo or bimekizumab 64mg, 160mg, 160mg (320mg loading dose [LD]) remained on the same dose; non-responders (<PASI90 at Week 12) were re-assigned from placebo/bimekizumab 64mg to 160mg or from 160mg/160mg (LD) to 320mg. Patients previously receiving bimekizumab 320mg/480mg received 320mg. The primary variable was the exposure-adjusted incidence rate (EAIR) of treatment-emergent adverse events (TEAEs); efficacy assessments were secondary.

Results: 217 patients were enrolled. Across all doses, BE ABLE 1 responders generally maintained complete or almost complete skin clearance for up to an additional 48 weeks: PASI90: 80–100%, non-responder imputation (93–100%, observed); PASI100: 70–83% (80–96%); Investigator's Global Assessment: 78–100% (98–100%). PASI100 was achieved by 33–76% (40–82%) of non-responders (Week 48). EAIR of TEAEs was 206.1/100 patient-years (n=184/217 [85%]). EAIR of serious TEAEs was 6.2/100 patient-years (n=15/217 [7%]); no serious TEAE was reported by >1 patient. The most frequent TEAEs were oral candidiasis and nasopharyngitis. No cases of suicidal ideation/behaviour, major adverse cardiac events, or inflammatory bowel disease were reported. No new safety findings were observed.

Conclusion: Nearly all BE ABLE 1 responders completing 60 weeks of bimekizumab treatment maintained complete or almost complete skin clearance, with a safety profile consistent with previous studies.³

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Acknowledgement: The study was funded by UCB Pharma.

Disclosure of Interests: Andrew Blauvelt Grant/research support from: AbbVie, Aclaris, Akros, Allergan, Amgen, Boehringer Ingelheim, Celgene, Dermavant, Dermira Inc, Eli Lilly and Company, Galderma,

Genentech/Roche, GlaxoSmithKline, Janssen, LEO, Meiji, Merck Sharp & Dohme, Novartis, Pfizer, Purdue Pharma, Regeneron, Revance, Sandoz, Sanofi Genzyme, Sienna Pharmaceuticals, Sun Pharmaceuticals, UCB Pharma, Valeant, Vidac, Consultant for: AbbVie, Aclaris, Akros, Allergan, Almirall, Amgen, Boehringer Ingelheim, Celgene, Dermavant, Dermira Inc., Eli Lilly and Company, Galderma, Genentech/Roche, GlaxoSmithKline, Janssen, LEO, Meiji, Merck Sharp & Dohme, Novartis, Pfizer, Purdue Pharma, Regeneron, Revance, Sandoz, Sanofi Genzyme, Sienna Pharmaceuticals, Sun Pharmaceuticals, UCB Pharma, Valeant, Vidac., Speakers bureau: Janssen, Regeneron, Sanofi Genzyme, Kim A. Papp Grant/research support from: AbbVie, Akros, Allergan, Amgen, Anacor, Arcutis, Astellas, Baxalta, Boehringer Ingelheim, Bristol-Meyers Squibb, Can-Fite Biopharma, Celgene, Coherus, Dermira, Dow Pharma, Eli Lilly, Galderma, Genentech, Gilead, GlaxoSmithKline, InflaRx GmbH, Janssen, Kyowa Hakko Kirin, LEO, MedImmune, Merck (MSD), Merck-Serono, Moberg Pharma, Novartis, Pfizer, PRCL Research, Regeneron, Roche, Sanofi-Aventis/Genzyme, Takeda, UCB Pharma, Valeant/Bausch Health, Consultant for: AbbVie, Akros, Amgen, Arcutis, Astellas, AstraZeneca, Baxalta, Baxter, Boehringer Ingelheim, Bristol-Meyers Squibb, Can-Fite Biopharma, Celgene, Coherus, Dermira, Dow Pharma, Eli Lilly, Forward Pharma, Galderma, Genentech, Janssen, Kyowa Hakko Kirin, LEO, Meiji Seika Pharma, Merck (MSD), Merck-Serono, Mitsubishi Pharma, Novartis, Pfizer, PRCL Research, Regeneron, Roche, Sanofi-Aventis/Genzyme, Takeda, UCB Pharma, Valeant/Bausch Health, Speakers bureau: AbbVie, Amgen, Astellas, Celgene, Eli Lilly, Galderma, Janssen, Kyowa Hakko Kirin, LEO, Merck (MSD), Novartis, Pfizer, Sanofi-Aventis/Genzyme, Valeant/Bausch Health, Joseph F. Merola Consultant for: Biogen IDEC, Abbvie, Amgen, Eli Lilly and Company, Novartis, Pfizer, Janssen, UCB, Samumed, Celgene, Sanofi Regeneron, Merck, and GSK, Alice B. Gottlieb Grant/research support from: Incyte Corporation, Janssen Ortho Inc, Lilly ICOS LLC, Novartis, UCB, XBiotech, Consultant for: AbbVie, BMS, Celgene Corporation, Dermira, Incyte Corporation, Janssen Biotech, Janssen Ortho Inc, LEO Pharma, Lilly ICOS LLC, Novartis, Sun Pharmaceuticals Ltd, UCB, Speakers bureau: AbbVie, Eli Lilly and Company, Janssen Biotech, Nancy Cross Employee of: UCB Biosciences Inc, Cynthia Madden Shareholder of: UCB Biosciences Inc, Employee of: UCB Biosciences Inc, Maggie Wang Employee of: UCB Biosciences Inc, Christopher Cioffi Shareholder of: UCB Biosciences Inc, Employee of: UCB Biosciences Inc, Christopher E.M. Griffiths Grant/research support from: AbbVie, Celgene, LEO, Lilly, Janssen, Novartis, Pfizer, Sandoz, UCB Pharma, Speakers bureau: AbbVie, Almirall, Bristol-Meyers Squibb, Celgene, Galderma, Janssen, Lilly, Novartis, Pfizer, Sandoz, UCB Pharma
DOI: 10.1136/annrheumdis-2019-eular.4166

AB0739

THE PREVALENCE OF PSYCHOLOGICAL DISORDERS IN PATIENTS WITH SEVERE PSORIASIS WITH/WITHOUT PSORIATIC ARTHRITIS IN CLINICAL PRACTICE: DATA FROM A SINGLE DERMATOLOGICAL SETTING

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Background: Psoriatic arthritis (PsA) and Psoriasis (PsO) are associated with different psychological disorders. Depression is a risk factor for development of PsA among PsO patients (pts). Diagnosis of PsA in dermatological practice is still problematic. The prevalence of psychological disorders in patients with severe PsO with/without PsA are limited in the Russian Federation.

Objectives: To study the prevalence of anxiety, depression and fatigue in pts with severe PsO with/without PsA in a single dermatological setting.

Methods: 99 unselected pts (male-23/female-76) with severe plaque PsO, mean age 45.82±14.04 years, BSA 56.35±9.11%, PASI 22.50 ± 5.13 were included. PsA was diagnosed by the CASPAR criteria. Anxiety, depression and fatigue were identified by the Hospital Anxiety Scale (HADS-A), HADS-Depression (HADS-D) and Functional Assessment of Chronic Illness Therapy (FACIT) (points) accordingly. The HADS-A/HADS-D was defined as normal - 0-7; presence of disorders - 8-10; psychiatric morbidity >11 points accordingly. FACIT 43.6±9.4 matched with healthy control. The lower the level of FACIT corresponded to higher fatigue. The number of pts with FACIT≤30 were calculated. All pts were treated with different synthetic DMARDs, mostly Methotrexate (subcutaneous 15-20 mg every week), biological DMARDs according local therapy according